DEPARTMENT OF HEALTH AND HUMAN SERVICES

MAY 15 1998

Dr. Alan McHughen
Crop Development Center
University of Saskatchewan
51 Campus Drive
Saskatoon SK S7N 5A8
Canada

Dear Dr. McHughen:

This is in regard to your genetically modified flax variety, CDC Triffid, about which you initiated consultations with the Agency on October 2, 1997. According to the submission, the new flax variety produces acetolactate synthase (ALS protein), which is derived from *Arabidopsis*, and confers tolerance to sulfonylurea herbicides.

As part of bringing your consultation with FDA regarding this product to closure, you submitted a summary of your safety and nutritional assessment concerning CDC Triffid flax on October 27, 1997, and February 6 and 10, 1998. These communications informed FDA of the steps taken by you to ensure that the product complies with the legal and regulatory requirements that fall within FDA's jurisdiction. Based on the safety and nutritional assessments you have conducted, it is our understanding that you have concluded that flax seed derived from the new variety is not materially different in composition, safety, and other relevant parameters from flax seed currently on the market, and that the genetically modified flax does not raise issues that would require premarket review or approval by FDA. All materials relevant to this notification have been placed in a file designated BNF0050. This file will be maintained in the Office of Premarket Approval.

Based on the information you have presented to FDA, we have no further questions concerning CDC Triffid flax at this time. However, as you are aware, it is your responsibility to ensure that foods marketed by you are safe, wholesome and in compliance with all applicable legal and regulatory requirements.

Sincerely yours,
/S/
Alan M. Rulis, Ph.D.
Director
Office of Premarket Approval
Center for Food Safety
and Applied Nutrition

cc:HFS-200 HFS-205 HFS-206 HFS-226 HFS-235 HFS-246 HFS-247 HFS-13
HFV-144 HFV-151 HFV-200 HFV-221 HFV-228 **BNF 0050**